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Thielen et al.

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(54) **AUTOMATIC VASCULAR CLOSURE DEPLOYMENT DEVICES AND METHODS**

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This patent is subject to a terminal disclaimer.

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(52) **U.S. Cl.**
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CPC A61B 17/0057; A61B 17/0467; A61B 17/0487; A61B 2017/00654; A61B 2017/00663; A61B 2017/0417; A61B 2017/0496; A61B 2019/4836
See application file for complete search history.

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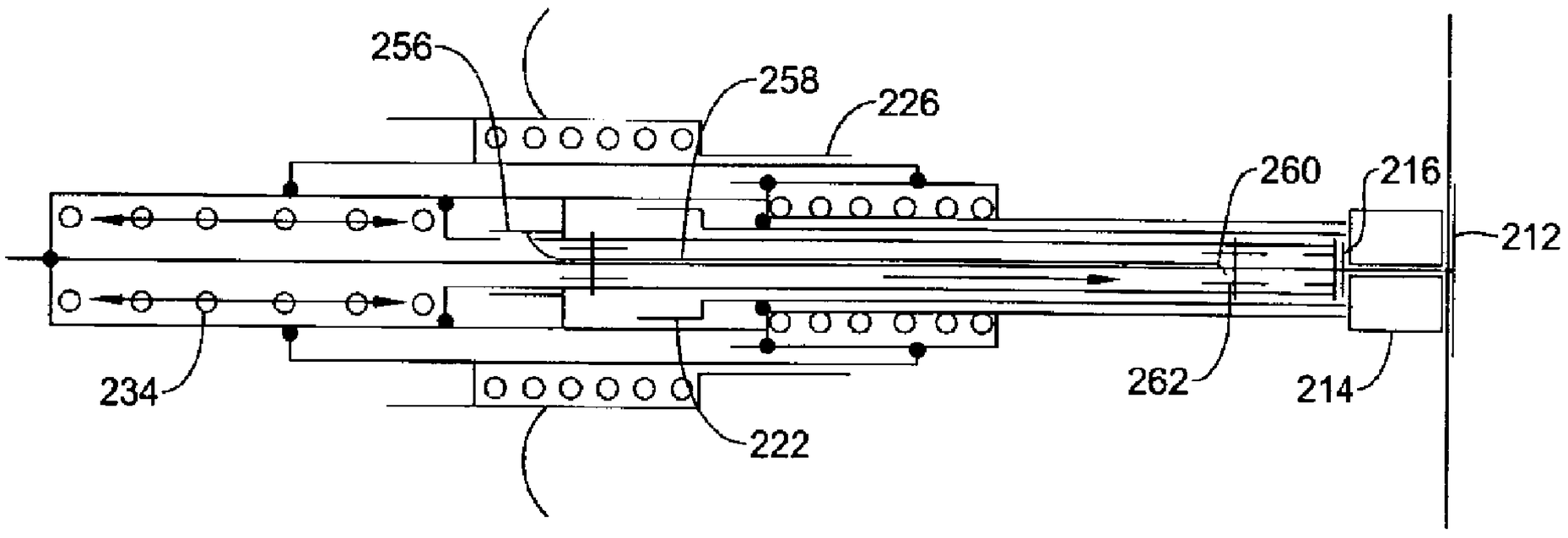
(57) **ABSTRACT**

Methods of installing a vascular closure device, the vascular closure device adapted for sealing an opening in biological tissue and comprising an anchor, a compressible plug, a cinch and a suture, the method comprising the steps of providing an insertion sheath, inserting the insertion sheath into the opening in the biological tissue, providing a device sheath having the vascular closure device preloaded therein with a proximal portion of the suture attached to the device sheath, subsequent to the step of inserting the insertion sheath, inserting the device sheath into the insertion sheath, and retracting the insertion sheath and device sheath simultaneously, wherein during the retraction, the insertion sheath and the device sheath are fixed to one another and devices adapted to the methods.

16 Claims, 19 Drawing Sheets



(51) **Int. Cl.**
A61B 17/00 (2006.01)
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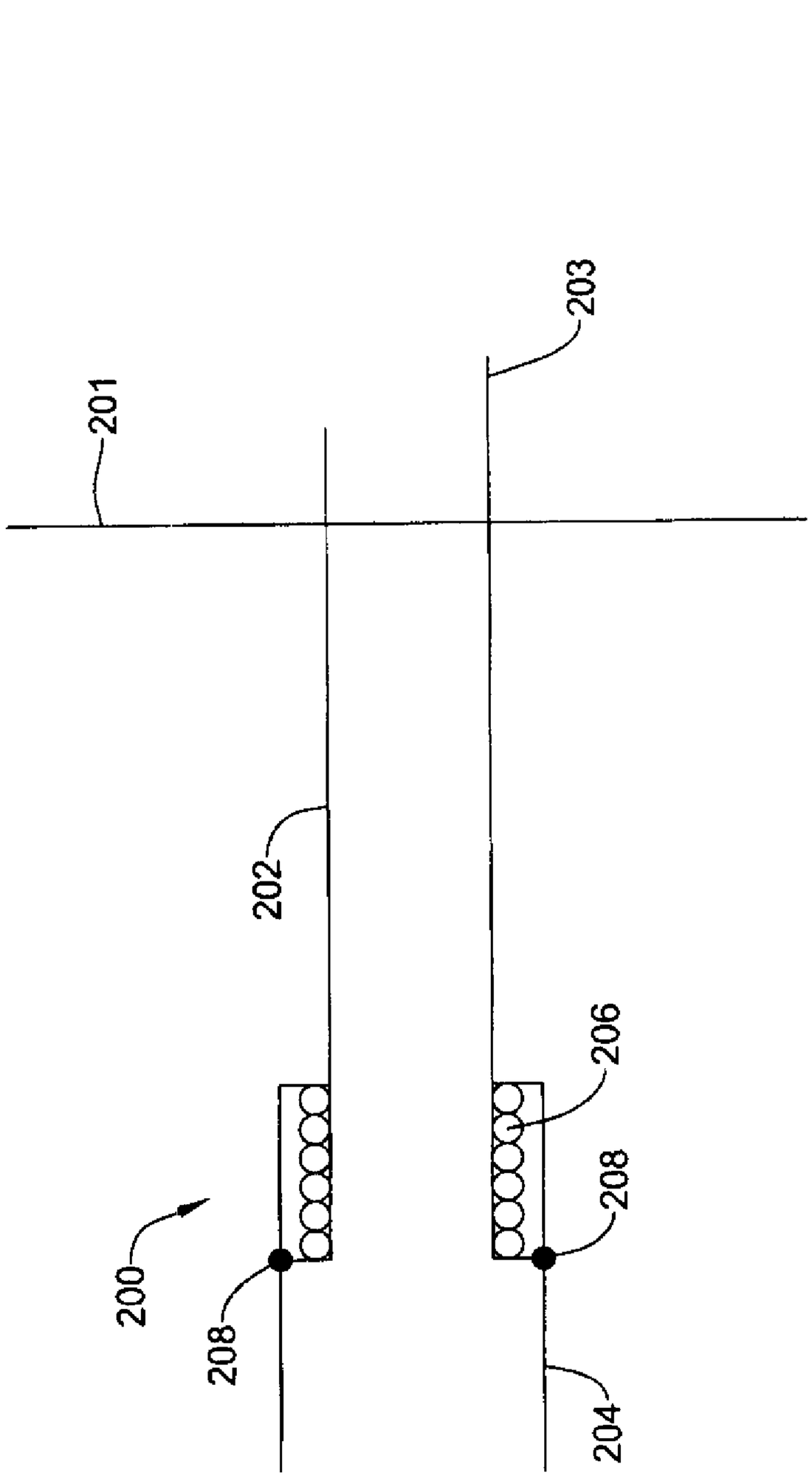

Figure 1

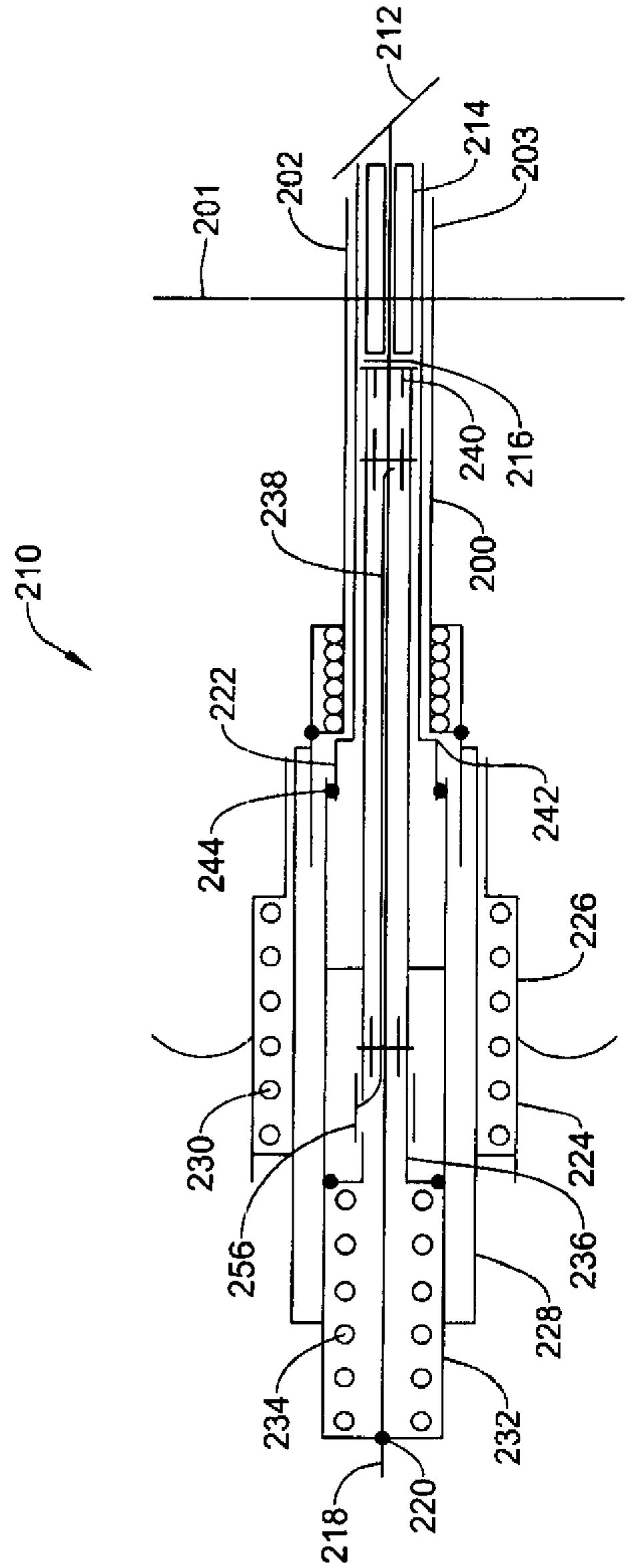
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Figure 2

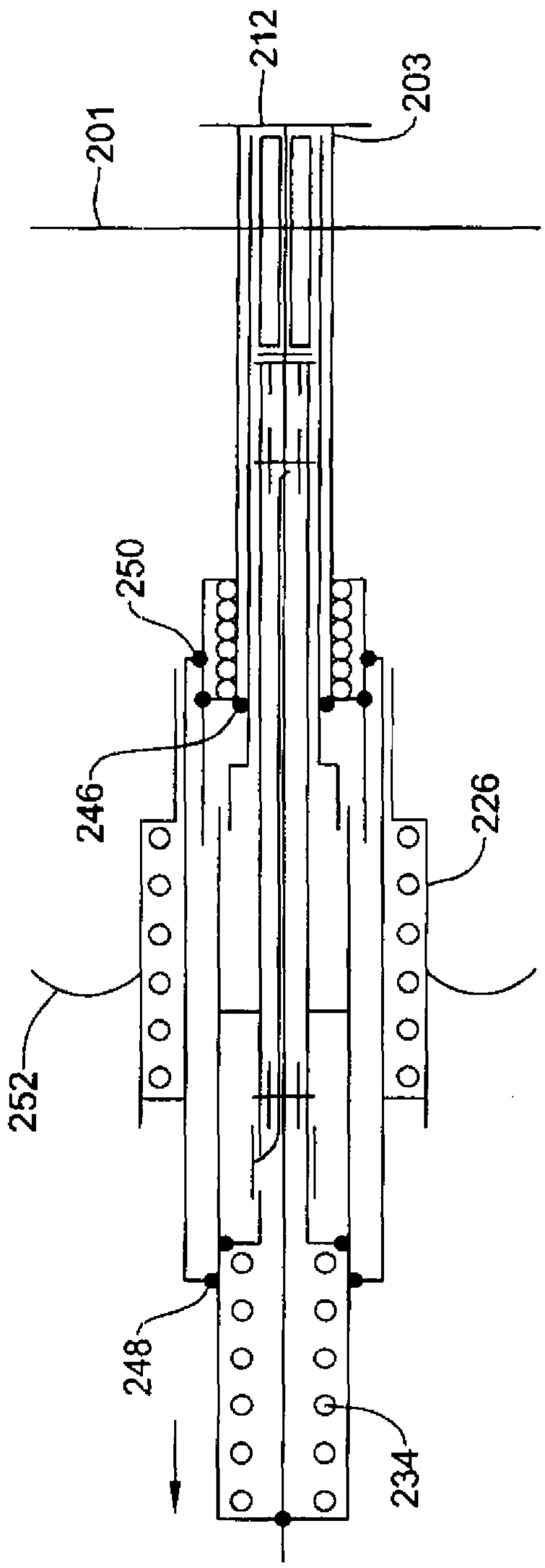


Figure 3

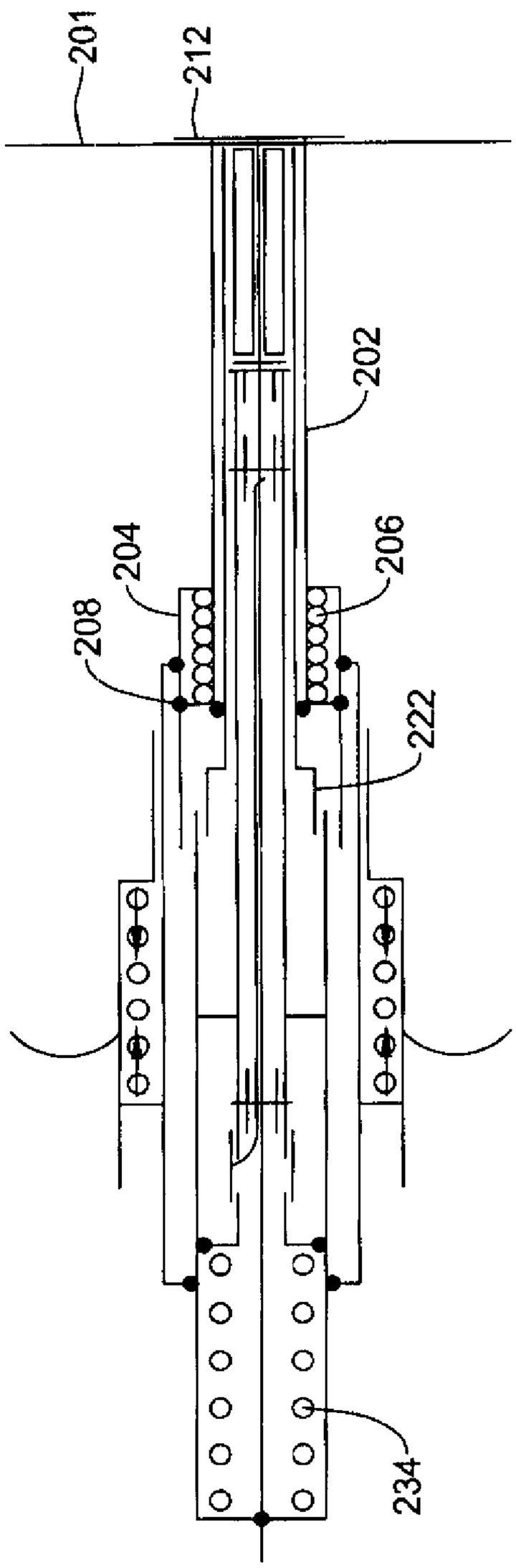


Figure 4

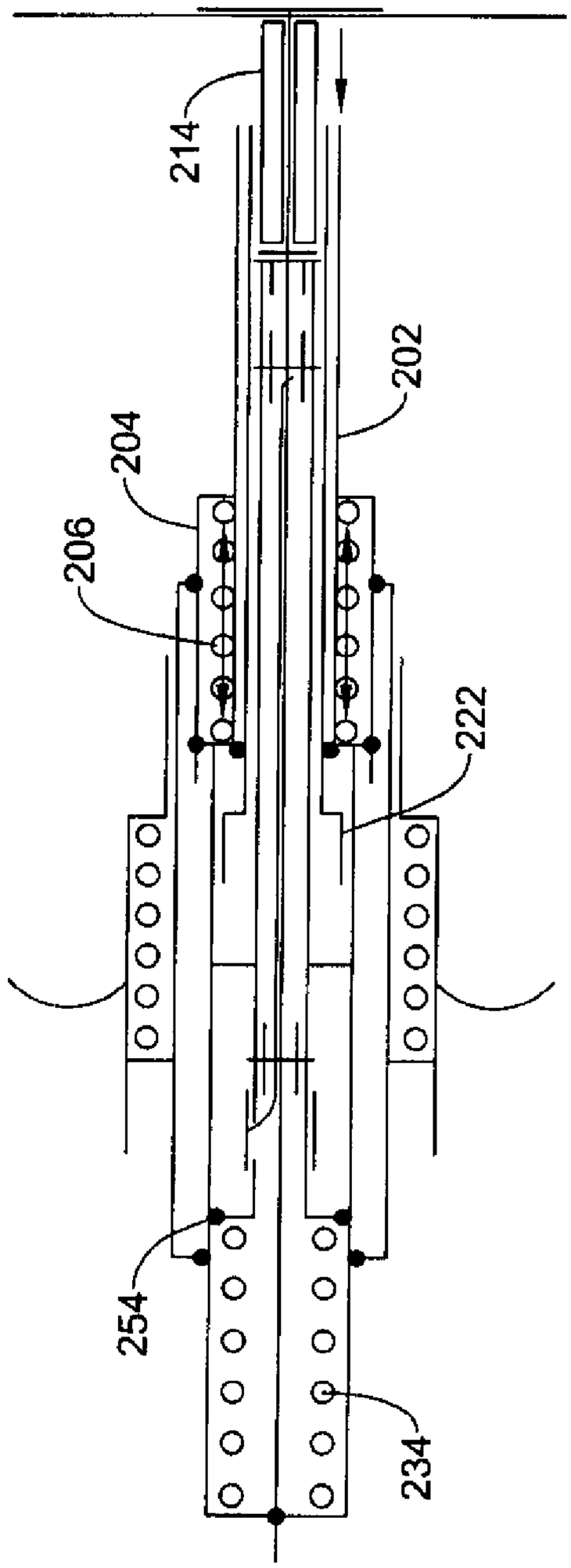


Figure 5

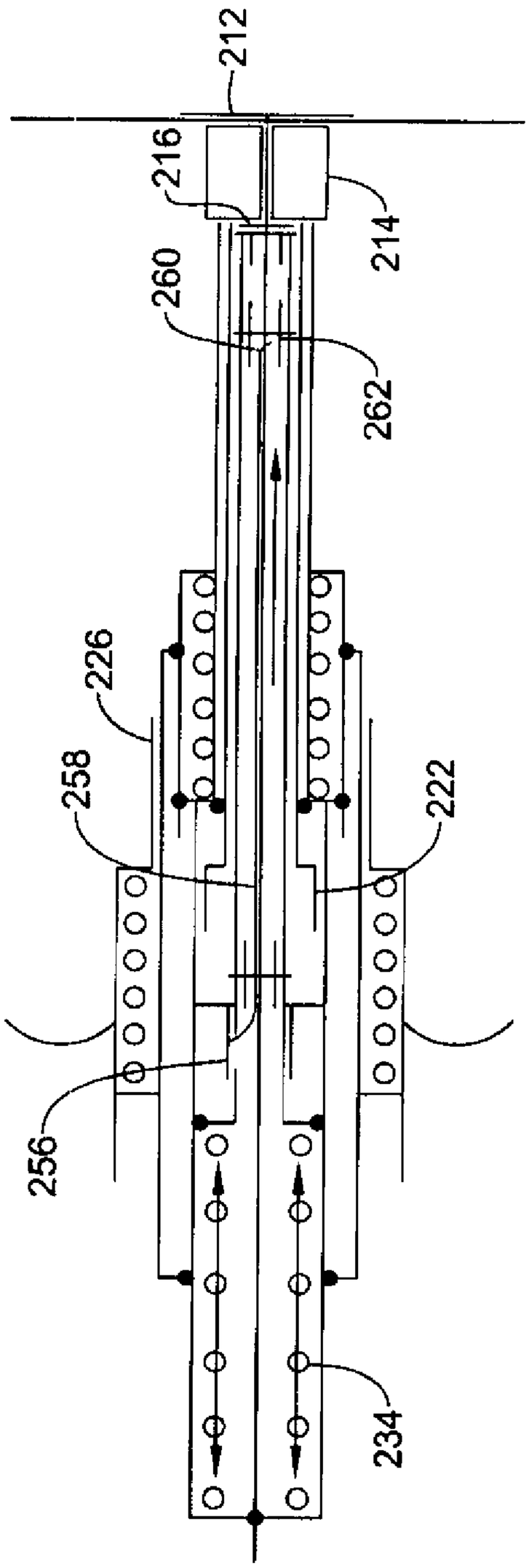


Figure 6

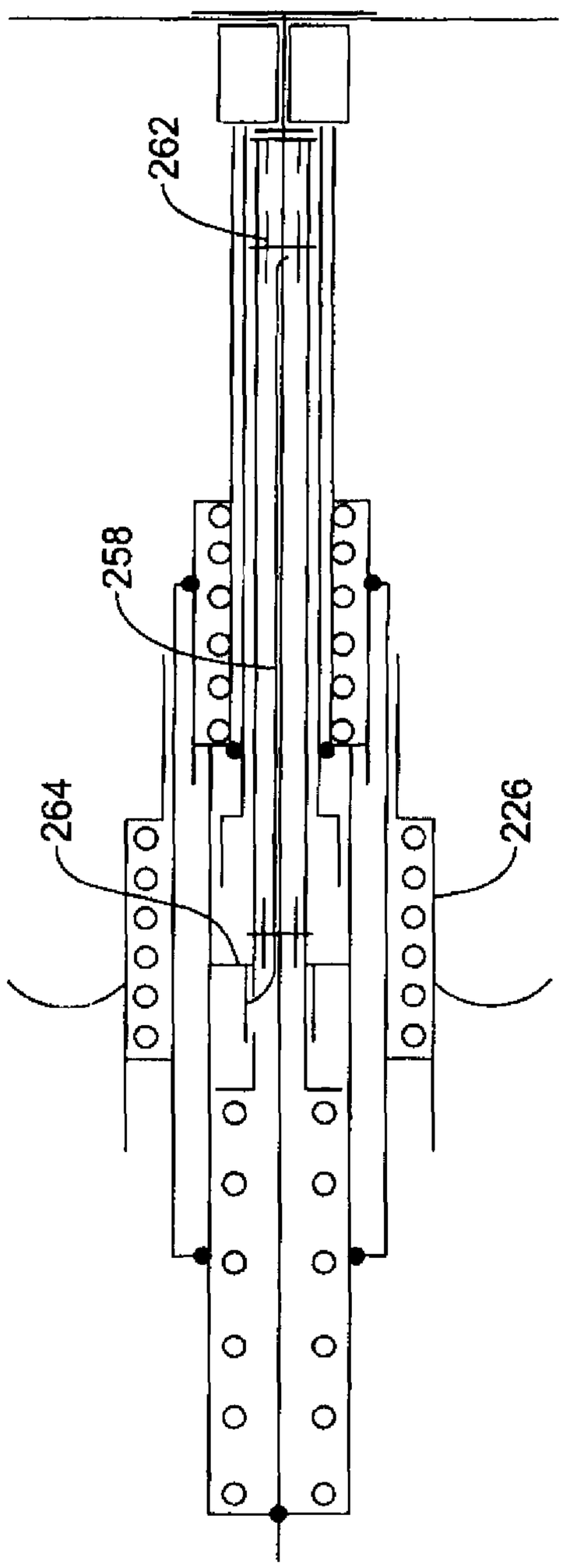


Figure 7

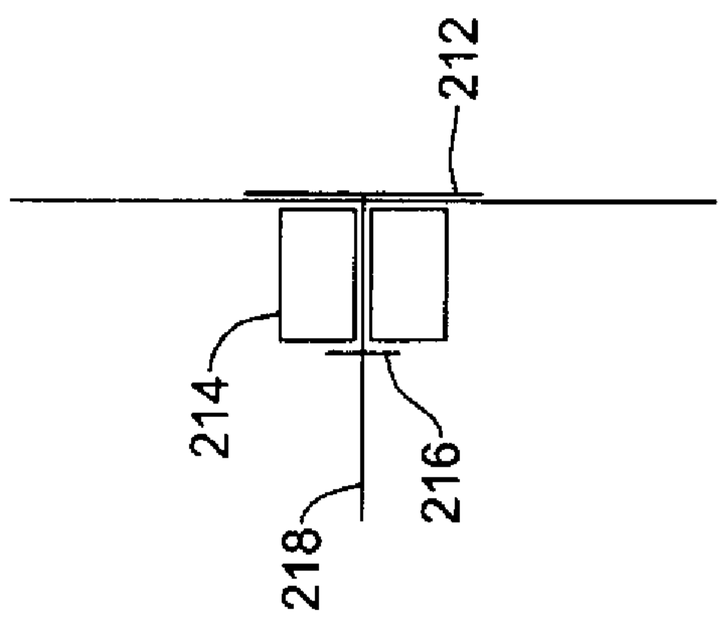


Figure 8

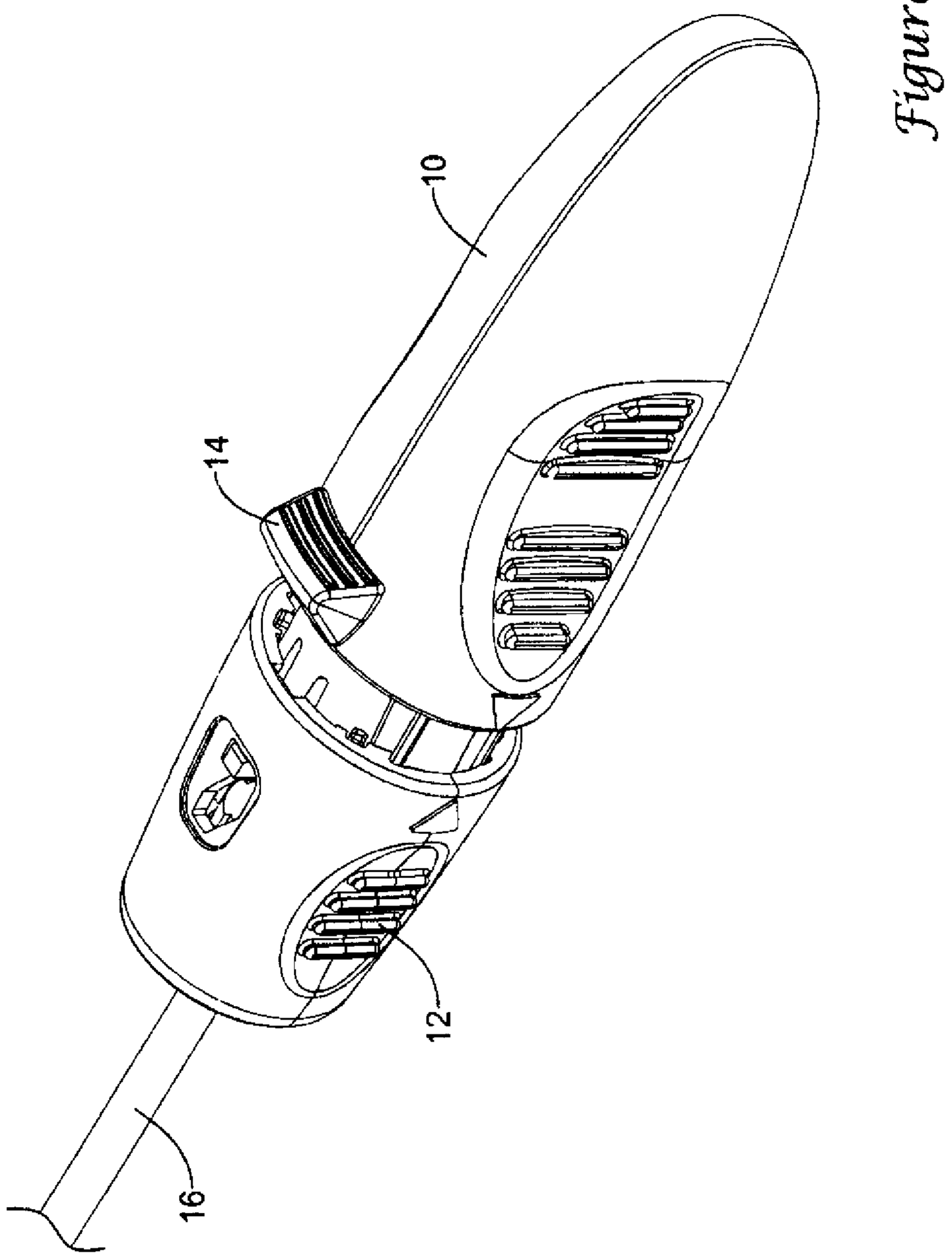


Figure 9

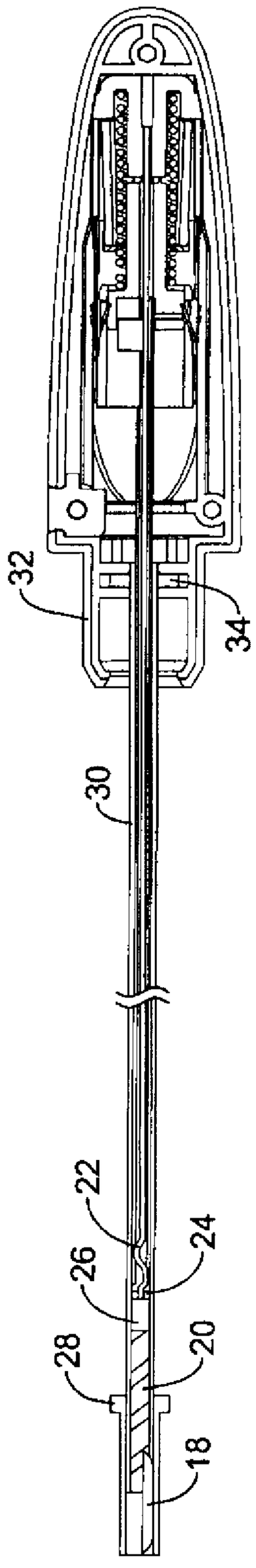


Figure 10

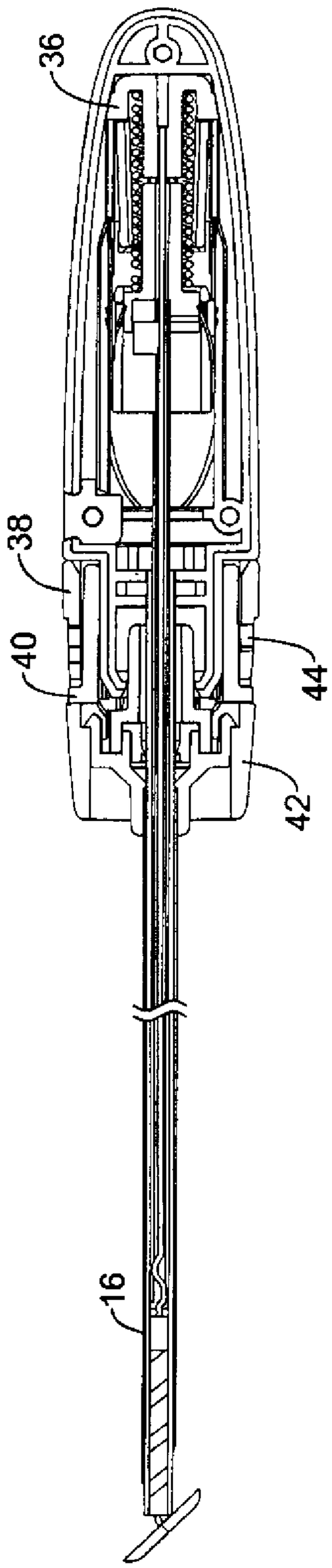


Figure 11

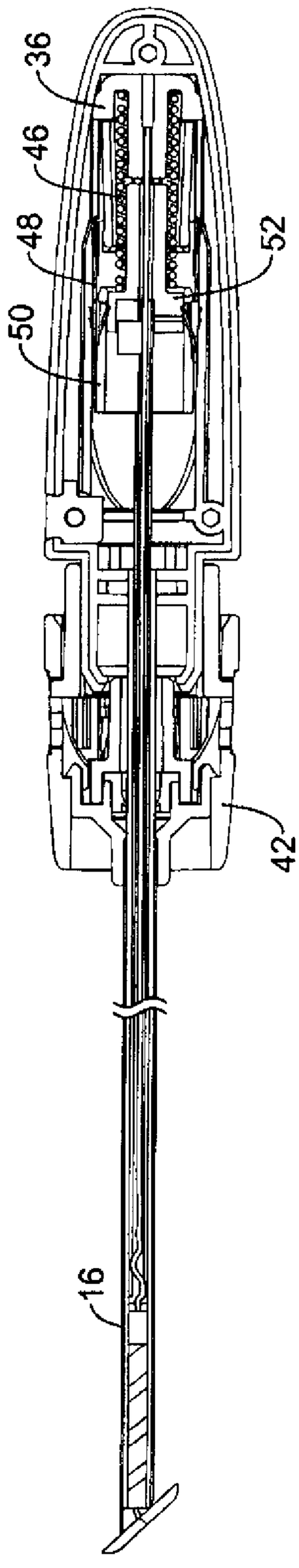


Figure 12

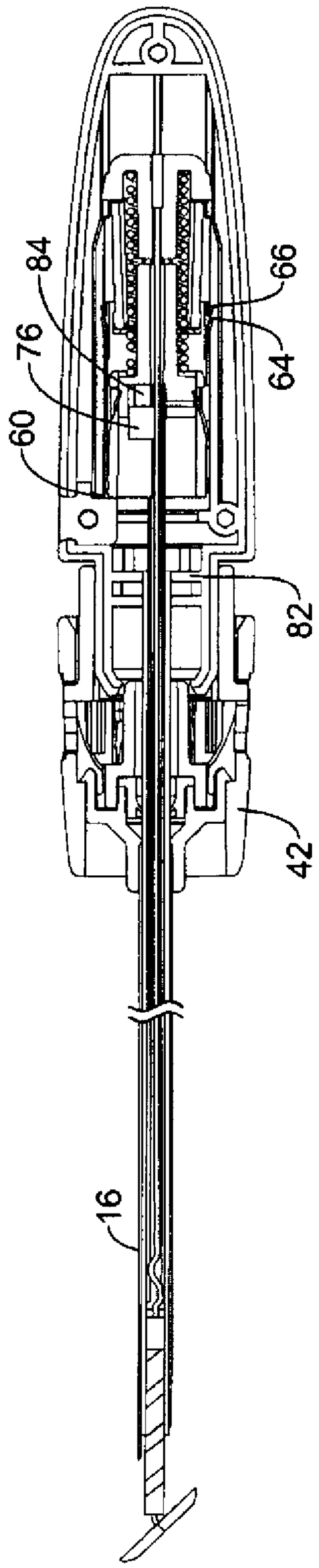


Figure 13

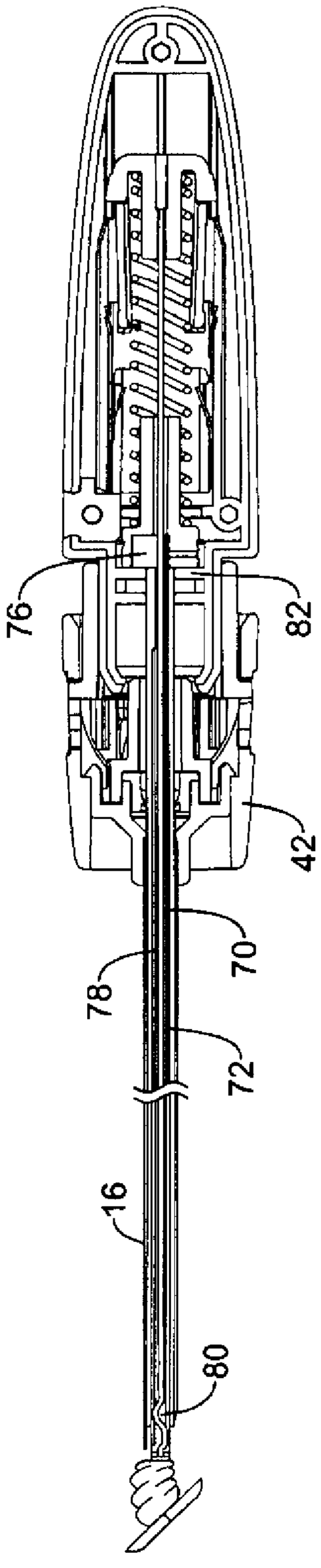


Figure 14

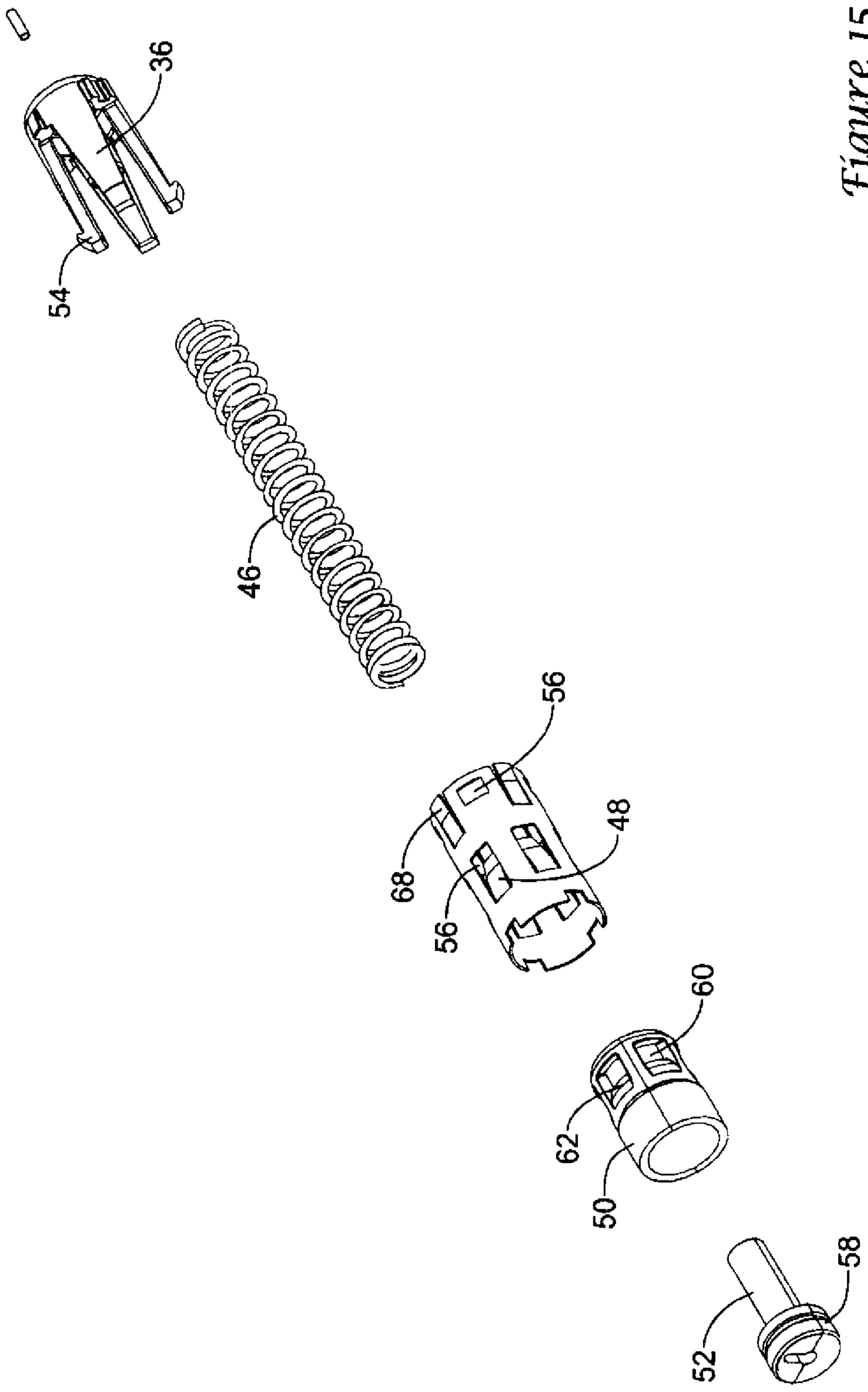


Figure 15

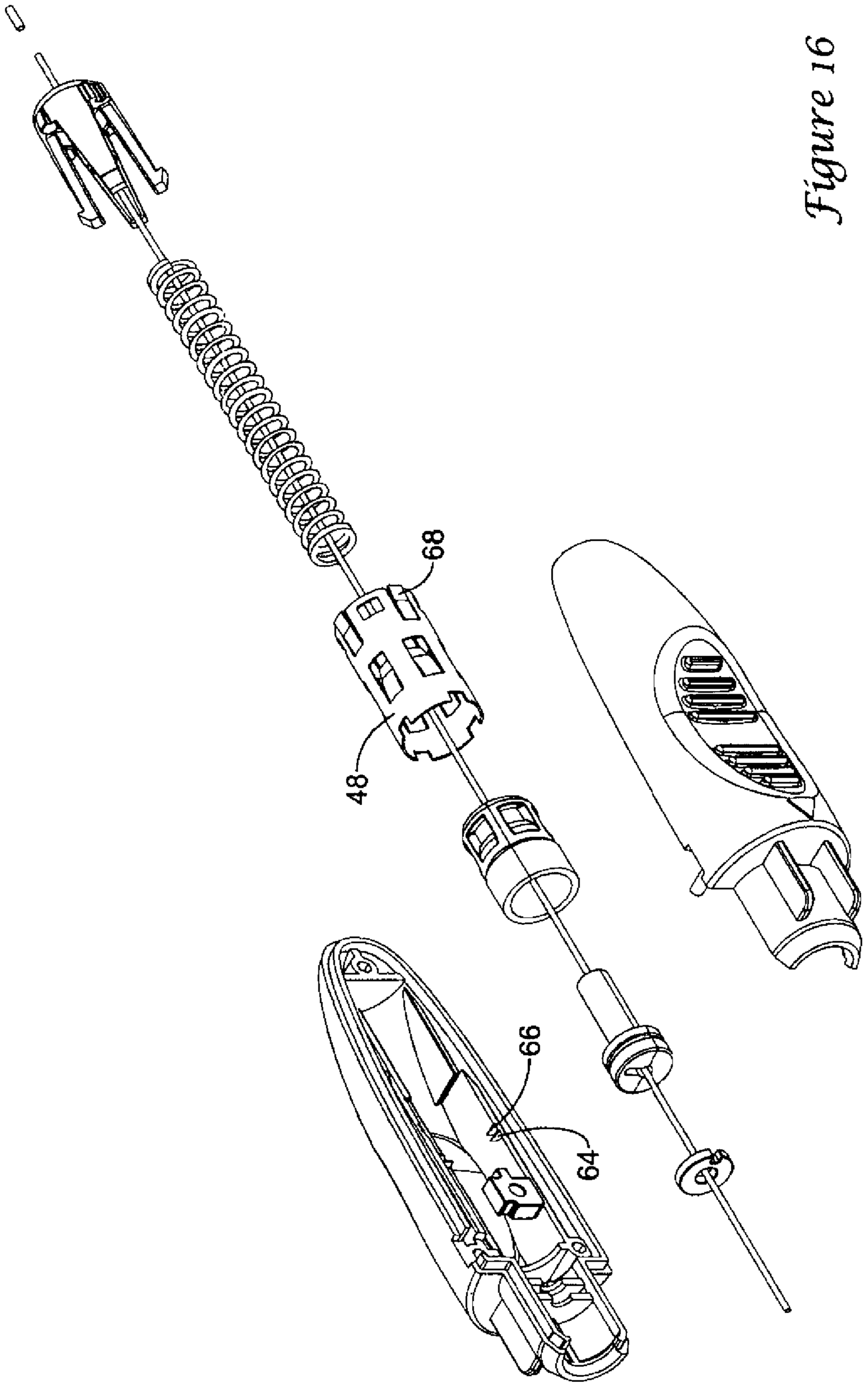
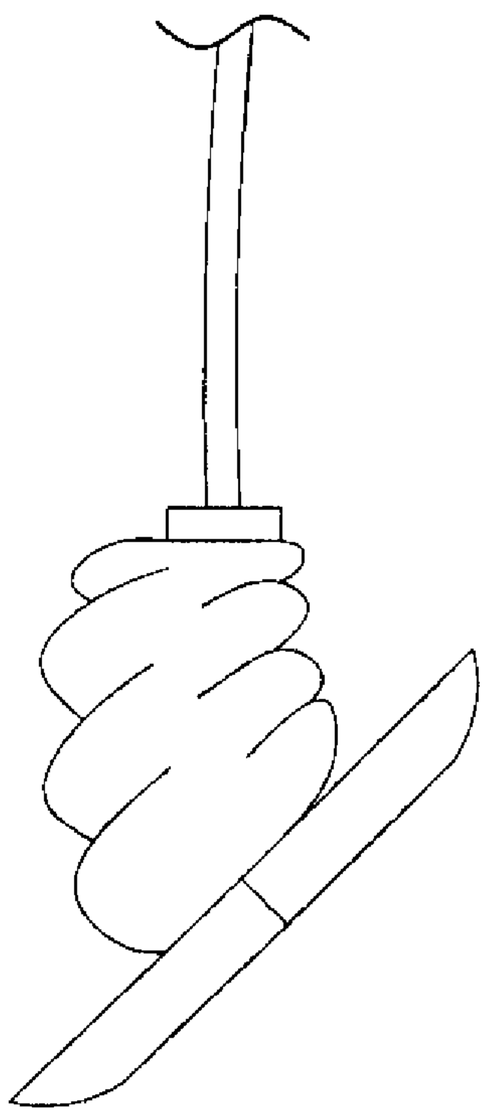


Figure 16

Figure 17



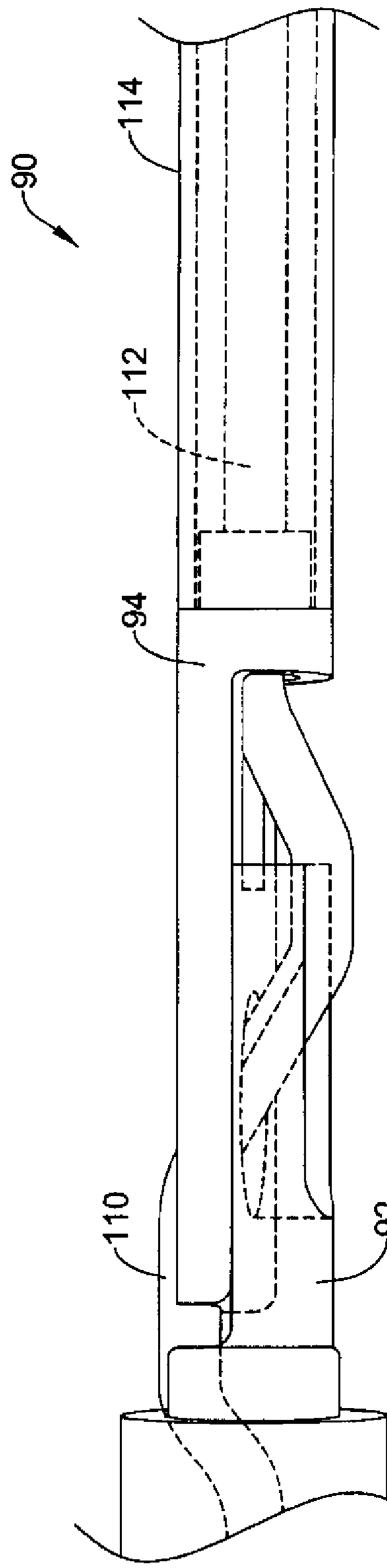


Figure 18A

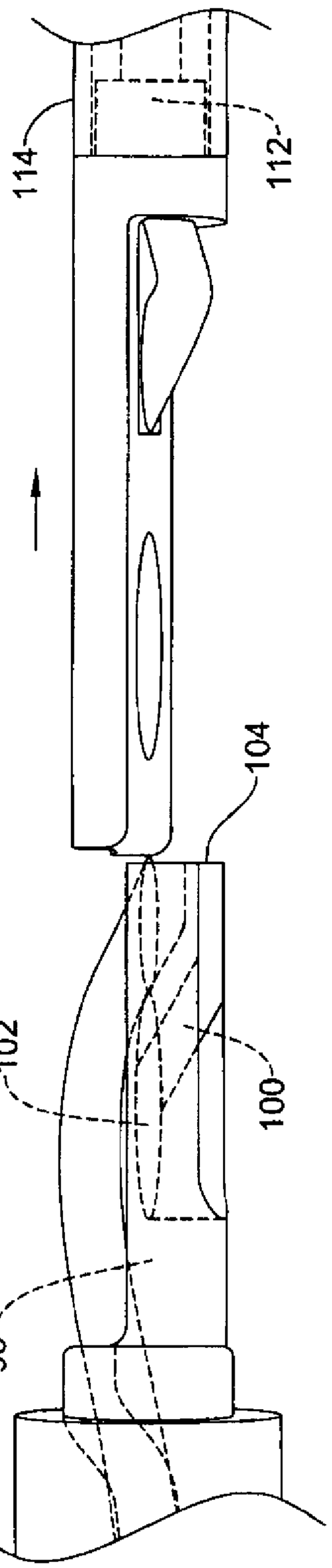


Figure 18B

Figure 19A

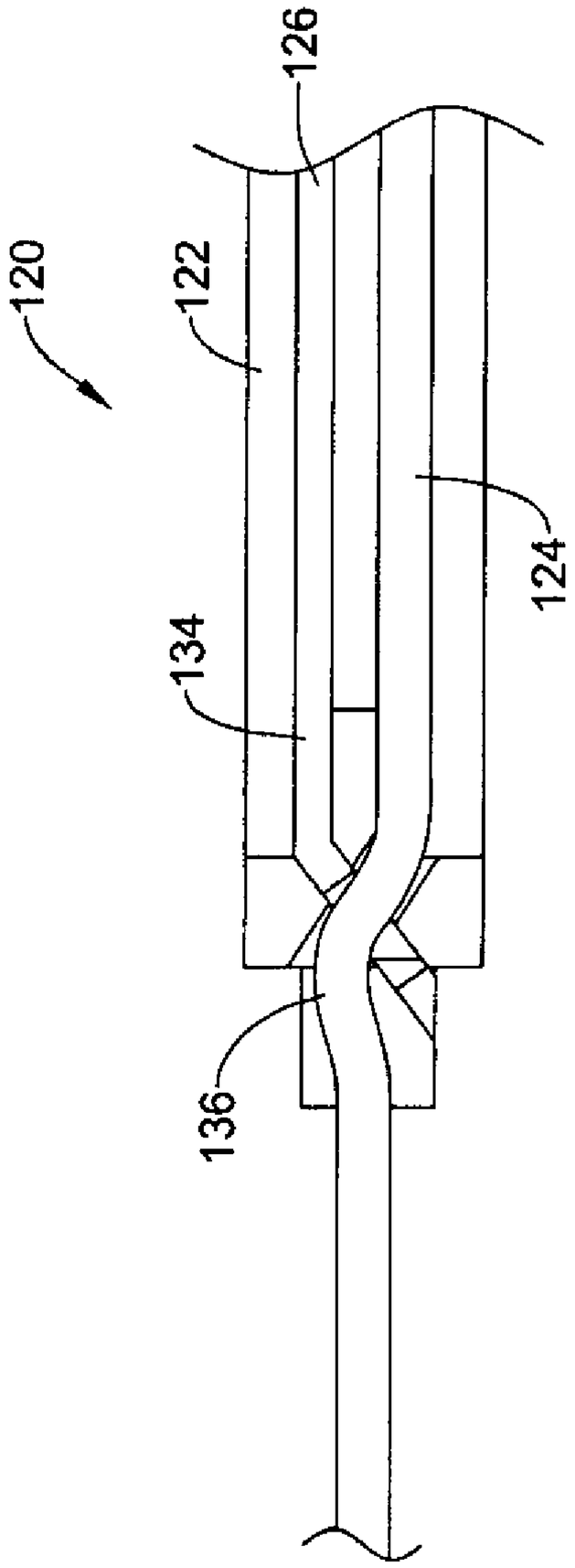
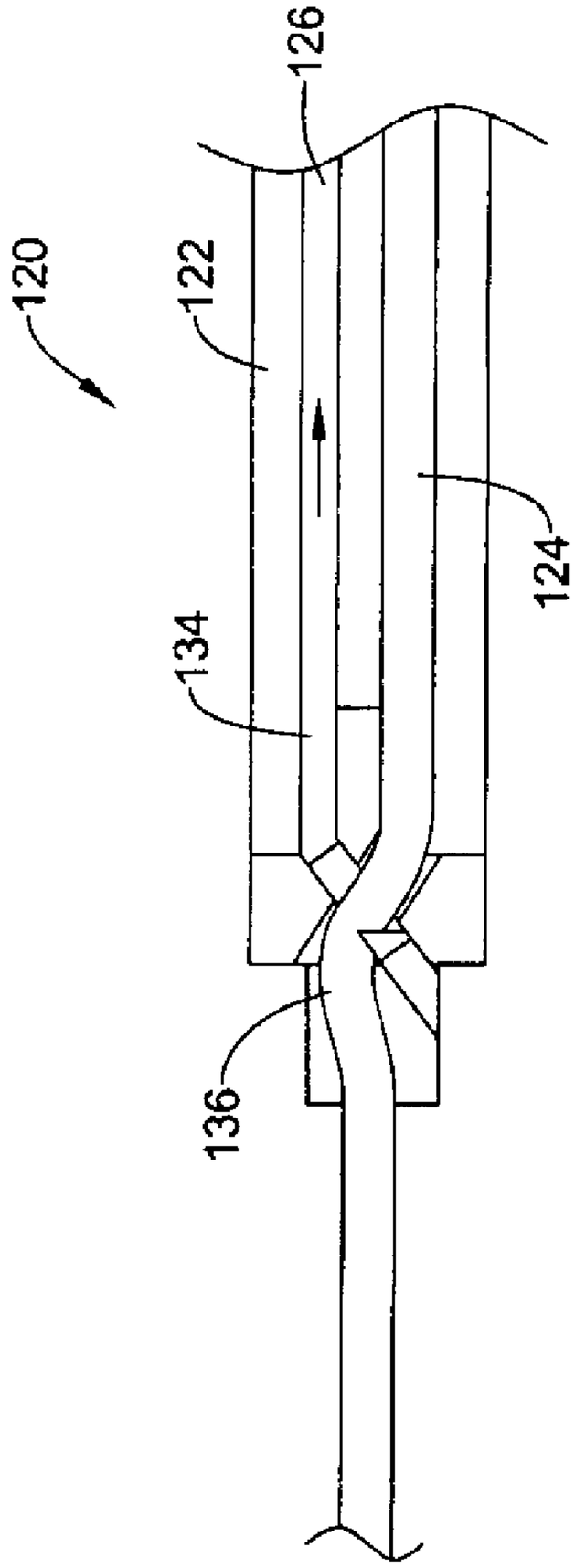


Figure 19B



AUTOMATIC VASCULAR CLOSURE DEPLOYMENT DEVICES AND METHODS

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/025,356, filed Feb. 11, 2011, now U.S. Pat. No. 8,444,673, which claims priority to U.S. Provisional Application Ser. No. 61/337,748, filed Feb. 11, 2010.

FIELD OF THE INVENTION

The present invention relates generally to medical devices and methods for sealing and closing passages formed through tissue. More specifically, the present invention relates to apparatuses or devices for sealing or closing an opening formed through biological tissue to control, prevent or stop bleeding or other biological fluid or tissue.

BACKGROUND

In many medical procedures, such as, for example, balloon angioplasty and the like, an opening can be created in a blood vessel or arteriotomy to allow for the insertion of various medical devices which can be navigated through the blood vessel to the site to be treated. For example, after initial access with a hollow needle, a guidewire may first be inserted through the tissue tract created between the skin, or the epidermis, of the patient down through the subcutaneous tissue and into the opening formed in the blood vessel. The guidewire is then navigated through the blood vessel to the site of the occlusion or other treatment site. Once the guidewire is in place, an introducer sheath can be slid over the guide wire to form a wider, more easily accessible, tract between the epidermis and the opening into the blood vessel. The appropriate medical device can then be introduced over the guidewire through the introducer sheath and then up the blood vessel to the site of the occlusion or other treatment site.

Once the procedure is completed, the medical devices or other equipment introduced into the vessel can be retracted through the blood vessel, out the opening in the blood vessel wall, and out through the tissue tract to be removed from the body. The physician or other medical technician is presented with the challenge of trying to close the opening in the blood vessel and/or the tissue tract formed in the epidermis and subcutaneous tissue. A number of different device structures, assemblies, and methods are known for closing the opening in the blood vessel and/or tissue tract, each having certain advantages and disadvantages. However, there is an ongoing need to provide new and improved device structures, assemblies, and/or methods for closing and/or sealing the opening in the blood vessel and/or tissue tract.

Arteriotomy closure after diagnostic and/or interventional catheterization procedures has been addressed by a number of devices in addition to standard manual compression. One of the most successful approaches has been the use of a collagen plug placed external to the artery, held in place by a biodegradable polymer (such as PLGA) anchor inside the artery, with these two components held together by a suture which passes through the arteriotomy. The components are essentially cinched together to stabilize the components in place with arterial wall tissue pinched between the plug and anchor to maintain approximation for a period of time before sufficient clotting, tissue cohesion, and/or healing occurs to prevent significant bleeding complications. While this approach has had success, there are drawbacks with these devices. The primary problems are that bleeding complications still occur,

arterial occlusion problems occur, and there are many steps required to properly implant these devices which require effort by the practitioner, training, and careful attention to various manually-performed steps to reduce the occurrence of complications. One step common to most of the prior approaches has been trimming of the cinching suture at the conclusion of the procedure. This is typically performed by pulling tension on the suture manually, depressing the skin manually, and trimming the suture manually. The suture is trimmed close to the depressed skin so that when the skin is released, the ends of the suture are underneath the surface of the skin. This is important to reduce infections which would be more likely if the suture extends to the skin because this would maintain an access path from outside the body through the normally protective skin layer to the tissues underneath. This is typically not a difficult procedure, but nevertheless represents steps which are presently performed manually, taking more time than necessary, and must be done carefully to trim the suture to the correct length. It may be desired to trim the suture a bit farther underneath the skin than is easily accomplished by this method; this may be desired to minimize infection risks, for example. The present invention overcomes these problems by providing an apparatus which automates the suture cutting, and can easily cut the suture at a location deeper under the skin if desired, providing a faster procedure and an improved safety margin for trimming location.

Prior art devices require complex techniques that require many steps to properly implant these devices. This requires training and careful attention to various manually-performed steps to reduce the occurrence of complications. The present invention overcomes these problems by providing an apparatus which automates the implantation procedure, thereby providing more reliable sealing, and reducing the complexity of using the device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of an introducer sheath **200** passing through a vessel wall **201**;

FIG. **2** is a schematic view of a device sheath **210** with a vascular closure device loaded therein inserted into the introducer sheath of FIG. **1**;

FIG. **3** is a schematic view of the introducer sheath **200** and device sheath **210** combination during a step of a process of deploying the vascular closure device;

FIG. **4** is a schematic view of the introducer sheath **200** and device sheath **210** combination during a step of a process of deploying the vascular closure device;

FIG. **5** is a schematic view of the introducer sheath **200** and device sheath **210** combination during a step of a process of deploying the vascular closure device;

FIG. **6** is a schematic view of the introducer sheath **200** and device sheath **210** combination during a step of a process of deploying the vascular closure device;

FIG. **7** is a schematic view of the introducer sheath **200** and device sheath **210** combination during a step of a process of deploying the vascular closure device;

FIG. **8** is a schematic view of a deployed vascular closure device;

FIG. **9** is an isometric view of the proximal portion, including the handle, of a device sheath;

FIG. **10** is a cross-sectional view of a device sheath with a vascular closure device loaded therein;

FIG. **11** is a cross-sectional view of the device sheath of FIG. **10** inserted into an introducer sheath;

FIG. **12** is a cross-sectional view of the device sheath and introducer sheath of FIG. **11** during a step of a process of deploying the vascular closure device;

FIG. **13** is a cross-sectional view of the device sheath and introducer sheath of FIG. **11** during a step of a process of deploying the vascular closure device;

FIG. **14** is a cross-sectional view of the device sheath and introducer sheath of FIG. **11** during a step of a process of deploying the vascular closure device;

FIG. **15** is an exploded view of certain interior components of an introducer sheath;

FIG. **16** is an exploded view of the proximal portion of an introducer sheath;

FIG. **17** is a view of a deployed vascular occluder device;

FIG. **18**A is a side view of a suture cutting mechanism with a suture therein;

FIG. **18**B is a side view of a suture cutting mechanism with a cut suture therein;

FIG. **19**A is a side schematic view of a suture cutting mechanism with a suture therein; and

FIG. **19**B is a side schematic view of a suture cutting mechanism with a partially cut suture therein.

DESCRIPTION

The following summary is provided to facilitate an understanding of some of the innovative features unique to the present disclosure and is not intended to be a full description. A full appreciation of the disclosure can be gained by taking the entire specification, claims, drawings, and abstract as a whole.

The present disclosure relates generally to medical devices and more particularly to methods and devices for closing and/or sealing punctures in tissue. In one illustrative embodiment, a device is provided for delivering and deploying an anchor, plug, filament and locking mechanism adjacent to the opening in the vessel wall and/or tissue tract. In some cases, the anchor may be automatically seated against the vessel wall. In some cases, the plug is compressed and the filament is trimmed automatically. In some cases, the anchor is seated, the plug is compressed and the filament is trimmed automatically.

The invention pertains to apparatuses and methods for implantation and deployment of an anchor-plug-cinch vascular closure device. The implantation and deployment apparatus may comprise an automated plug deployment mechanism having actuation means, drive mechanism, automatic sheath retraction mechanism, automatic anchor seating mechanism, automatic cinching mechanism, optional cinching speed control means, and automated suture trimming or release. The mechanism provides automatic cinching of an extravascular plug towards an intravascular anchor with controlled plug compression. The cinching motion can be controlled to a variable rate by various means such as orifice flows or springs or electro-magnetic-mechanical speed governing to provide for reduced actuation forces to minimize damage to the plug material and the anchor. For example, a gradual acceleration or deceleration period, with different velocity or driving force than other portions of the cinching travel, can be used to avoid tearing the plug, or bending or breaking the anchor. Various steps in the deployment process are accomplished automatically in the desired sequence while minimizing required user action.

The anchor-plug-cinch vascular closure device comprises an anchor, a plug, and a cinch and is similar to those described in of application Ser. No. 12/390,241, filed Feb. 20, 2009, which is incorporated by reference in its entirety herein. The implanted components (anchor, plug, cinch) are preferably degradable so that over time they are degraded or eroded and no longer present in the body. For example, the anchor can comprise PLGA, PLLA, or PGA, but other degradable or erodable polymers can be utilized for this purpose, such as polyesters, polysaccharides polyanhidrides, polycaprolactone, and various combinations thereof, especially if a different strength—degradation time profile is desired. The cinch can comprise these materials as well; for example, a biodegradable suture can be utilized as a tension member. One or more cinching or locking elements, such as a sliding cinch disk or knot, can be utilized to secure the cinch; a bonding or latching mechanism can also be utilized to secure the cinch. The plug preferably comprises a material which swells significantly to fill space in the tissue adjacent to the artery, such as by elastic expansion, fluid absorption, chemical reaction, and so forth, so that it provides improved hemostasis. The plug can comprise the aforementioned materials as well, but collagen, gelatin, PEG, and related materials and combinations can be used also. Dense collagen material has been used for this purpose, but is relatively stiff and provides little swelling. High void-volume gelatin foam or collagen foam, PEG, and similar materials offer more compressibility for smaller-profile introduction, and/or greater swelling for improved hemostasis. Other materials can be utilized which provide for control of hydration, or thrombogenicity, to improve the function of the plug; various combinations of these can be utilized, generally degradable or erodable materials are preferred.

The implantation and deployment apparatus provides automated deployment of the anchor-plug-cinch vascular closure device. The implantation and deployment apparatus comprises elongated components for introduction of the anchor, plug, and cinch into the body, including an insertion sheath and dilator, with an orientation indicator, a hub with a hemostatic valve and an elongated thinwalled tube formed with a distal bevel to accommodate the anchor at the desired deployment angle for proper approximation to the artery. A locating mechanism is incorporated, such as a bleed path in the insertion sheath and dilator for locating the sheath at the desired location in the artery.

The implantation and deployment apparatus further comprises a device sheath which passes through the insertion sheath and is affixed to a handle. The anchor of the anchor-plug-cinch vascular closure device is disposed in or adjacent to the distal end of the device sheath for introduction into the body. The anchor is affixed to the distal end of an elongated portion of the cinch mechanism (herein referred to as the "suture"). The suture extends through the device sheath. The plug is disposed proximal to the anchor and within the device sheath and is captured or retained by the suture. A cinching or locking element (herein referred to as the "cinch disk") is disposed adjacent and proximal to the plug and within the device sheath. The implantation device also includes a push rod (typically tubular) which passes through the proximal portion of the device sheath to the plug. During the deployment procedure, the push rod, suture, plug, device sheath, and anchor pass through the insertion sheath so that the anchor just passes out the end of the insertion sheath but other components largely do not.

The handle is affixed to the device sheath and comprises a body portion, a hub connector portion, an actuation portion (optionally automatic), an automatic anchor seating mechanism, a sheath retraction mechanism (optionally automatic), an automatic cinching mechanism, and optionally comprises

a suture trimming mechanism (optionally automatic); other grasping, orienting, indicating, and control elements can be incorporated.

The hub connector portion attaches to the insertion sheath hub, in a single orientation so that the relative orientation of the handle (and device sheath) and the insertion sheath (and bevel) are maintained when attached.

The actuation portion provides for arming the device and/or triggering the actions of the device. The actuation portion can include a lock or latch which is actuated by user manipulation. The actuation portion can include a latch or button which triggers the various retractions and cinching and other actions of the device in sequence. The actuation can be by application of force such as by pulling back on a portion of the delivery system after the anchor is in place in the vessel. The actions can all occur in sequence from a single trigger, or multiple triggering manipulations can be used to cause multiple sequences of device actions or single actions. Whether by manual or automatic retraction, the device is retracted until the anchor is seated snugly against the vessel wall.

The suture is attached to the automatic anchor seating mechanism. The automatic anchor seating mechanism can be activated by attachment of the hub connector portion of the handle body to the insertion sheath hub; the mechanism then retracts the suture and anchor (and may also retract other components such as the device sheath, plug, and cinch disk) relative to the introduction sheath a predetermined distance proximally to snug the anchor up against the beveled end of the insertion sheath. The automatic anchor seating mechanism can incorporate a speed limiting feature if desired to slow the movement and give the anchor sufficient time to move into alignment with the insertion sheath bevel, such as by incorporating a dashpot or other inertial or frictional mechanism; a moderate strength spring, for example, can retract the suture at an appropriate speed. The anchor seating mechanism has sufficient travel to accommodate any elongation of the suture.

The sheath retraction mechanism provides an appropriate sheath to anchor gap to allow proper deployment of the plug. Displacement can be provided to produce the desired sheath to anchor gap by paying out a predetermined length of suture, by sliding of a suture mounting element, by retraction of the device sheath hub relative to the introduction sheath hub, or by other means. Actuation of the sheath retraction mechanism can be automatically triggered, for example, by application of an appropriate retraction force by the user to pull the anchor against the vessel wall. One or more latches can be provided so that upon completion of the movement of the automatic anchor seating mechanism, automatic sheath retraction mechanism, or other mechanisms, the mechanism latches so to prevent further unwanted movement even if force is applied.

The automatic cinching mechanism advances the cinch disk, advances and axially compresses the plug (which deploys by radially expanding) and cinches the plug against the anchor. The cinching mechanism can be automatically triggered, for example, at the completion of the sheath retraction mechanism travel, or by application of an appropriate retraction force higher than the force which triggered the sheath retraction mechanism, or by manually pressing a button or releasing a latch, or by other means. The cinching mechanism also advances the cinch disk which maintains the implanted device in a cinched configuration after the procedure. When the cinching mechanism is completely actuated, the suture can be cut or otherwise released by an automatic suture cutting or release mechanism, which releases the suture from device so that the handle, device sheath, push rod, and insertion sheath can be withdrawn, leaving the anchor, plug, suture, and cinch disk in place. If an automatic suture cutting or release mechanism is not utilized, the skin is depressed an the suture trimmed to length manually so that it does not extend out past the skin.

The hub connector portion of the handle and/or the insertion sheath hub preferably have orientation features such as asymmetric shapes or pins or slots, etc., which allow the hub connector portion of the handle to mate with the insertion sheath hub in only one orientation, and which facilitate the attachment of the two pieces. Other shapes than those indicated in the drawings for the hub can be utilized, such as, for example, varying aspect ratios, angles, insertion depth, male/female, D- or squared- or rounded-components, convex/concave.

Some internal features and mechanisms which perform the described functions are not indicated in the figures to better illustrate the overall function of the invention. Such internal mechanisms can include, for example, springs, latches, levers, pulleys, strings, friction fits, dashpots, gas reservoirs.

In the embodiment described below with references to FIGS. **1-8**, certain conventions are used. Figures schematically illustrate the steps. (In the figures, the bevel is not shown, and the orientation is perpendicular to the artery for simplicity of illustration. Some latches are indicated diagrammatically as dots.)

The preferred method of achieving arteriotomy closure comprises the following steps. The steps are typically, but not necessarily, performed in the order listed. Certain steps can be combined or performed separately by configuration of the internal mechanisms. Preferably, steps are performed automatically as indicated. Alternatively, certain steps could include manual actuations, although this is less advantageous.

FIG. **1** is a schematic illustration of an insertion sheath **200**. The insertion sheath **200** is inserted over a guidewire after an interventional procedure (such as an angioplasty or stent deployment procedure). The insertion sheath **200** preferably includes a distal hemostatic seal (not shown) and a position indicator near the distal tip of the insertion sheath, which may provide an inlet for a bleed path which may flow through the insertion sheath to indicate the position of the insertion sheath relative to the vessel wall opening or other suitable indicator. Such features are described in the '241 application incorporated by reference above.

The insertion sheath preferably includes an insertion sheath tube **202** and an insertion sheath hub **204**. In this embodiment, the insertion sheath **200** has a spring **206** or other force mechanism which can move the insertion sheath tube **202** distally relative to the insertion sheath hub **204** when the latch **208** is released in a subsequent step.

The distal end of the insertion sheath tube **202** is preferably beveled as shown at **203** and a corresponding indicator is placed on the proximal portion of the tube or on the hub so that the orientation of the bevel can be known by observation of the proximal portion of the insertion sheath. The bevel is omitted in other figures for ease of illustration.

In this step, the interventional procedure sheath is exchanged with the insertion sheath **200** and dilator over a guidewire. The insertion sheath **200** is positioned and oriented to the proper bevel angle using the orientation indicator and the distal end of the insertion sheath is positioned a predetermined distance inside the artery and past the artery wall **201** by using the bleed path or other indicator to indicate position. The insertion sheath is then held to retain proper position and the dilator and guidewire are removed.

The second step is shown schematically with reference to FIGS. **2** and **3**. In this step a device sheath **210** is inserted into the insertion sheath **200** until the distal portion of the insertion sheath **200** is fed through the haemostatic valve and the device sheath **210** engages the hub **204** of the insertion sheath **200** and preferably clicks into place. The device sheath has the anchor **212**, plug **214**, cinch disk **216** and suture **218** pre-loaded. The suture is attached to the device sheath at the proximal end **220** of the device sheath.

The device sheath **210** has a device sheath tube portion **222** and a handle portion **224**. The handle includes an outer portion **226** that is disposed over a first frame **228**. The outer portion **226** is shown in its further distal position relative to the first frame **228** and may be slid proximally relative to the first frame **228**. This proximal motion is opposed by a spring **230** disposed between the outer portion **226** and the first frame **228**.

The device sheath **210** also includes a second frame **232** disposed within the first frame **228**. This second frame **232** is initially fixed relative to the device sheath tube **222** and the components internal to the second frame **232** (discussed below) and may be moved relative to the first frame **228** and outer portion **226**. A spring **234** is held between the proximal end of the second frame **232** and a pushing plate **236**. At this point, the pushing plate **236** is still fixed to the second frame **232**. The pushing plate is attached to a pushing tube **238**. The pushing tube **238** has a compression plate **240** at its distalmost end, which abuts the cinch disk **216**.

The anchor **212** is seated against the beveled edged **203** of the insertion sheath tube **202** by pushing the device sheath **210** against the insertion sheath **200**. The device sheath tube **222** has a shoulder **242** that hits against the insertion sheath tube **202** to check the proximal movement of the device sheath tube **222**. As the device sheath **210** is still being moved distally relative to the insertion sheath **200**, this movement breaks a connection **244** between the device sheath tube **222** and the second frame **232**. The anchor **212** is fixed to the second frame **232** by the suture **218** at the proximal end **220**, and the anchor **212** therefore pushes the device sheath tube **222** proximally until the distal ends of the insertion sheath tube **202** and the device sheath tube **222** are proximate each other, as shown in FIG. **3**. The components are sized such that at this point, the anchor **212** is properly seated against the beveled distal tip **203** of the insertion tube **200**. When the device sheath tube **22** and the insertion sheath tube **202** are positioned so that the distal ends are proximate each other, the device sheath tube and insertion sheath tube are also fixed with respect to one another at latch **246**.

The second frame **232** continues to move proximally until it latches to the first frame **228** at latch point **248**, at which point the first frame and second frame are fixed relative to each other.

The device sheath **210** is move distally until the first frame **228** latches against the insertion sheath hub **204** at latch point **250**, which fixes the first frame and insertion sheath hub relative to each other.

Once the anchor **212** is seated against the distal end of the insertion sheath tube **202**, the whole device (**200** and **210**) may be pulled proximally by pulling on the outer portion **226**. This first seats the anchor plug **212** against the artery wall **201**, as shown in FIG. **4**. The function of the spring **230** disposed between the first frame **228** and outer portion **226** may be seen at this point. This spring **230** functions to control the amount of force transmitted from the outer portion **226** to the first frame **228**.

It is helpful to recall that at this point in the process, the first frame **228** is fixedly connected to the insertion sheath hub **204** and to the second frame **232**. The internal components not yet discussed are fixedly attached to the second frame **232**. The insertion sheath tube **202** is fixedly attached to the device sheath tube **222**. Finally, the insertion sheath tube **202** is also still attached to the insertion sheath hub **204**.

When the device (**200** and **210** together) is pulled proximally by pulling on the outer portion **226**, the anchor plug **212** positioned against the artery wall **201** prevents the device from being pulled from the patient's body. A force builds up in the mechanism. When a predetermined level of force is reached, the connection **208** between the insertion sheath hub **204** and the insertion sheath tube **202** is broken. This releases the spring **206** disposed between the insertion sheath tube **202** and hub **204**. This spring **206** expands to drive the insertion sheath tube **202** (and connected device sheath tube **222**) proximally relative to the insertion sheath hub **204**. This operates to retract the distal ends of the insertion sheath tube **202** and device sheath tube **222** from around the distal portion of the plug **214**, as shown in FIG. **5**.

The operator continues to pull the device (**200** and **210**) proximally by pulling on the outer portion **226**, which further compresses the spring **230** between the outer portion **226** and the first frame **228** to provide a greater force. This causes a second connection point **254** to release, between the second frame **232** and the pushing plate **236**. This allows spring **234** to expand to advance to the pushing plate **236** distally. As the pushing plate **236** is connected through the pushing tube **238** to compression plate **240** and as the suture is still connected at **220** to the second frame **232**, this motion advances the cinch disk **216** to compress and deploy the plug **214**. This is illustrated in FIG. **6**.

There are several further components that may be attached to the pushing plate **236** and pushing tube **238**. A suture cutting mechanism **256** may be friction fit to the pushing plate **236**. Suture cutting mechanisms will be discussed more fully below, but for the purposes of this embodiment, it is sufficient to say that the suture cutting mechanism includes a long pull wire **258** with a blade at **260** at the distal end. The blade at the distal end is disposed in or proximate to a shearing block **262**, which is fixed within the pushing tube **238**. The suture or filament is threaded through the shearing block **262** and/or blade **260** such that relative movement of the shearing block **262** and blade **260** may cut the suture.

Once the connection point **254** is released, the spring **234** at the proximal end of the second frame **232** pushes the pushing plate **236** distally to advance the cinch disk **216** to compress and deploy the plug **214** as described above. This spring **234** continues to expand and forces the suture cutting mechanism **256** against a stop **264**. This stop **264** is shown as part of the second frame **232**. At this point, the spring **234** forces the push plate **236** proximally relative to the suture mechanism **256**. Because the suture mechanism **256** is fixed to the blade **260** by the pull wire **258** and because the shearing block **262** is fixed within the push tube **238** which is still being pushed by the push plate **236**, relative movement between the blade **260** and the shearing block **262** is created, which cuts the suture **218**. This is illustrated schematically in FIG. **7**.

The device (**200** and **210**) is still pulled proximately by the outer portion **226**. As the device is no longer attached to the anchor **212**, this serves to retract the device from the body, leaving the anchor **212**, plug **214**, cinch disk **216** and suture **218** distal portion cinched to the artery wall to provide hemostasis, as illustrated in FIG. **8**.

Since many of the actions occur automatically, the procedure is streamlined from a user perspective. The user steps condense to the following:

1. Swap the interventional sheath for the insertion sheath **200** and position the insertion sheath **200** using bleed indicator.

2. Hold the insertion sheath position, and insert the device sheath **210** until it engages the insertion sheath hub **204** (the anchor **212** automatically seats against the insertion sheath bevel **203**).

3. Retract the device handle **224** to deploy the device and remove the delivery system (the sheath retraction, cinch mechanism, and suture cutting all happen automatically in sequence).

Prior art devices and procedures have more steps which must be performed by the user because certain automatic features incorporated into the present invention have previously been done manually by the user. The prior art is therefore more complicated to use. Also, the present invention accomplishes certain actions in an automatically controlled manner, making the performance of the device more reliable, less affected by the orientations, forces, and movement speeds applied by the user. For example, prior art devices typically do not have automatic seating of the anchor against the insertion sheath bevel. Also, prior art devices typically do not have automatic tension and compressive forces applied to the plug. Also, prior art devices typically do not cut the suture automatically upon proper plug deployment. These and other features streamline the use of the device and provide improved reliability over the prior art.

A second embodiment is illustrated with respect to FIGS. **9-17**. One difference between this embodiment and the previous embodiment is that the step of seating the anchor plug against the distal end of the insertion sheath tube is less automatic.

FIG. **9** is a view illustrating the proximal portion of a second embodiment. In FIG. **9**, the proximal portion of the device sheath **10** and the proximal portion of the insertion sheath **12** are shown. The device sheath is slid into the insertion sheath tube **16** but is not yet engaged with the device sheath.

The device sheath may optionally include a button **14** or other trigger mechanism, which is pushed to allow the automated process to start. Such a button **14** may be useful to prevent premature deployment of the process.

The insertion sheath **12** preferably includes a distal hemostatic seal (not shown) and a position indication near the distal tip of the insertion sheath, which may provide an inlet for a bleed path which may flow through the insertion sheath to indicate the position of the insertion sheath relative to the vessel wall opening or other suitable indicator. Such features are described in the '241 application incorporated by reference above.

In the first step, the insertion sheath is inserted over a guidewire after an interventional procedure (such as an angioplasty or stent deployment procedure). This step is not illustrated in these figures.

FIG. **10** is a cross-sectional view of a device sheath similar to that of FIG. **9** prior to the insertion of the device sheath into the insertion sheath. The anchor **18**, plug **20**, suture **22** and cinch disk **24** are preloaded in the device sheath and the proximal end of the suture is fixed to the second frame **36**. (An optional plug component **26** is shown in this figure). The anchor is kept in an insertion orientation by an orientation tube **28**. The device sheath tube **30** is fixed to the outer portion **32** by a fixation disk **34** or other suitable mechanism.

With reference to FIGS. **11** and **12**, the steps of inserting the anchor through the artery wall and seating the anchor against the distal end of the insertion sheath tube are described.

While the artery wall is not illustrated in these figures, it is contemplated that prior to FIG. **11**, the insertion sheath is already properly positioned through the artery wall. When the device sheath **10** is inserted into the insertion sheath **12**, the insertion sheath pushes the orientation tube **28** distally. The insertion sheath tube **16** keeps the anchor **18** in an insertion orientation until it deploys through the distal tip of the insertion sheath as illustrated in FIG. **11**. The orientation tube **28** is then housed within the device sheath hub **38** throughout the remainder of the procedure.

The device sheath is inserted until an insertion sheath collar **40** is locked to the device sheath by a detent (not shown) or other mechanism. This is the state in FIG. **11**.

The insertion sheath is then held in place by an operator holding onto hub **42** and the device sheath **10** is retracted proximally by the operator. This moves the collar **40** relative to the hub **42** until the collar is locked in a second position by a detent **44** or other mechanism, as shown in FIG. **12**. Because the insertion sheath tube **16** is fixed to the hub **42**, and the anchor, plug, cinch disk, suture and device sheath tube **30** are fixed relative to the device sheath, this moves those components relative to the insertion sheath tube **16** to seat the anchor **18** against the distal end of the insertion sheath tube as shown in FIG. **12**.

The operator releases the insertion sheath, and continues to withdraw the device sheath proximally. This first seats the anchor **18** against the inner wall of the artery and next starts to move the internal components of the device sheath distally relative to outer portion **32**.

Some of those internal components can be better seen with reference to FIG. **15**, which is an exploded view. Second frame **36**, spring **46**, first tube **48**, second tube **50** and pusher plate **52** are illustrated. These components may also be seen in cross-section in FIG. **12**, for example.

In the step of FIG. **12**, these internal components are positioned as follows. Tabs **54** of second frame **36** are in holes **56** of first tube **48**. These two components are fixed relative to each other throughout the procedure. Tabs **56** of first tube **48** are positioned through holes **60** of second tube **50** and the proximal ends of tabs **56** are disposed in slot **58** of pusher plate **52**. This is a circumferential slot. The spring is captured between second frame **36** and pusher plate **52**. The distal end of first tube **48** is somewhat proximal the distal end of second tube **50**.

When the operator continues to withdraw the device (moving from FIG. **12** to FIG. **13**), these internal components move distally relative to outer portion **32**. The distal end of second tube **50** hits a stop at **60**. The first tube is forced to continue moving distally by its connection to the second frame until its distal end also hits the stop at **60**.

The effect of this relative movement between first and second tubes **48** and **50** is to force tabs **48** to ride up on ramps **62**. This forces the proximal end of the tabs **48** radially apart, which moves them out of slot **58**. This releases spring **46**.

First tube **48** also includes tables **68**. These tabs **68** engage detents **64** and **66** as the internal components move proximally within outer portion **32**. These tabs thereby prevent the internal components from being moved distally one the detents have been reached. Detents **66** are engaged by tabs **68** when the proximal edge of the second tube **50** reaches the stop at **60**. Detents **64** are engaged by tabs **68** when the proximal edge of the second tube reaches the stop at **60**.

In FIG. **14**, one can see the effect of releasing spring **46**. Spring **46** drives pusher plate **52** distally, which pushes pusher

tube **70**, **72** to drive pushing end/shearing block **74** against cinch disk **24**. This compresses the plug **20**.

Also included in this embodiment are components related to the suture cutting mechanism. A suture cutting mechanism block **76** is connected by a tube **78** (located between the suture and the pusher tube) to a cutting block **80**. The suture is threaded through the cutting block **80** and the shearing block **74**. Block **76** is friction fit to pusher plate **52**. When the proximal end of block **76** reaches stop **82**, the block **76** is driven into a cavity **84** of the pusher plate **52**. Because the pusher plate is connected by pusher tube **70**, **72** to pushing end/shearing block **74**, and block **76** is connected by tube **78** to cutting block **80**, a relative movement is created between the shearing block **74** and the cutting block **80**, which cuts the suture.

At this point the device may be withdrawn, and the anchor, suture, plug and cinch disk are installed to create hemostasis.

Another embodiment of the invention is described with reference to FIGS. **18***a* and **18***b*. These figures illustrate the distal portion of an automatic suture cutter device **90**. The device **90** includes a shearing block **92** and a cutting element **94**. The shearing block includes a face **96** that abuts a corresponding face **98** of the cutting element. The faces **96** and **98** may be flat or may have another complementary shape. A lumen **100** is disposed in the shearing block **92**. The lumen **100** has a first opening **102** on the face **62** and a second proximal opening **104**. Lumen **102** angles away from opening **102** to create a sharp edge on the proximal side of the opening **102**. The cutting element **94** includes a corresponding lumen **106** with an opening **108** on face **98** and another opening (not shown) on the other side of the cutting block. Lumen **106** angles away from opening **108** to create a sharp edge on the distal side of opening **108**.

The cutting element **94** and the shearing block are initially aligned such that openings **102** and **108** are aligned. A suture **110** is threaded through the openings. The cutting element may then be retracted to cut the suture. The angled edges of the openings **106** and **108** act as a scissors to shear the suture.

The cutting element may include a proximal hole **112** to receive the suture and may be attached to a tube or wire **114**, which can be acted on to actuate the cutting mechanism. The shearing block **92** may include a central opening in the distal face through which the suture may be threaded. Both the shearing block and the cutting element are confined within a tube; this allows movement of the cutting element relative to the shearing block only along the direction of the arrow.

This suture cutting device may readily be incorporated into one or both of the embodiments described above. For example, shearing block **96** may correspond to shearing block **74** of the previous embodiment and cutting element **94** may correspond to cutting block **80**. The suture cutting may be triggered automatically as described above.

Another embodiment **120** of an automatic cutting mechanism is shown with respect to FIGS. **19***a* and **19***b*. This embodiment includes a tube **122** that has a suture lumen **124** and a cutting wire lumen **126**. A shearing block **128** is fixed to the tube and includes a first lumen **130** for the suture and a second lumen **132** for the cutting wire **134**. The first and second lumens cross in the shearing block. The cutting wire **134** has a distal end disposed in the cutting block and preferably has a loop (seen in cross section) with a cutting edge **136** on the inside of the loop. The loop is sized such that in a first position (shown in FIG. **19***a*), the cutting wire can be positioned so that it does not impinge on lumen **130**. When it is desired to cut the suture, the cutting wire **134** may be retracted proximally to sever the suture.

In this example, the shearing block has an angled hole through which the suture passes. The suture can move freely through the hole in either direction as needed by the delivery motions of the device. The cutting edge of the cutting element is initially positioned so that the suture is not contacted by the cutting edge until desired. The following figure illustrates the suture passing through the shearing block and other components. In this position, the suture is free to move relative to the cutter apparatus. The shearing block location within the device sheath, and the length of the cutting element, is chosen to cut the suture at a location long enough to minimize any risk of unintended suture release from the cinch disk, but short enough to be sufficiently far underneath the skin to minimize any risk of infection. Reduced length of suture also reduces the inflammatory response which occurs during biodegradation of a degradable suture.

The shearing block can be fixed at a particular location in the device sheath to allow enough space for the implantable portions, but little excess space. Alternatively, the shearing block can be advanced, such as together with the cinching movement, to follow the cinch disk and minimize the excess length of suture. The shearing block and cutting element can be advanced or retracted together at various stages in the deployment of the vascular closure device to provide for proper coordinated function of the deployment system. The following figure illustrates the cutter apparatus advanced along the suture; such advancement may be used during plug compression during vascular closure device deployment. The handle can have interacting features so that after the cinching movement occurs, the cutting element is automatically moved to cause the cutting of the suture. Alternatively, a manual actuator for the cutting element can be provided. The cutting movement of the cutting element can be either inward or outward, depending on the geometry of the cutting edge and shearing block. The present example shows the cutting element pulled back to cause the cutting of the suture.

After the suture is cut, the cutter mechanism is removed from the body; this motion may be combined with removal of the device sheath, handle, or other elements of the system. The removal may also be combined with retraction of the cutting element which produces the cutting, in an orderly or automatic manner. The following figure illustrates the cutting apparatus being removed after the suture has been cut. Other elements of the vascular closure device are not shown in these illustrations, but include an anchor, plug, and cinch disk, for example.

The suture cutter must be sufficiently flexible to allow for access and use; as examples, the cutter assembly extension can be made of a polymer, or slotted metal tube, which have sufficient strength but are flexible in bending.

In an automated version, the handle end of the cutting apparatus has steps, attachments, latch components, linkages or other features so that the motion of the cutter assembly extension, the cutting element, and the suture extension are actuated from the delivery system handle. The cutter can be advanced during plug compression, and the cutting element retracted to cut the suture, in a coordinated and automated manner during the device deployment sequence, using manual forces and displacements, latch release spring deployments, motor driven displacements, or other means.

The suture can be a continuous length of suture from the anchor, through the plug and cinch disk, all the way to the handle. A predetermined amount of suture extension can be accommodated, such as that obtained by a force-actuated triggering of the suture cutting. Alternatively, a shorter length of suture can be coupled to a suture extension such as a more rigid filament, wire or tube structure such as by swaging,

fastening using a tubing fastener, or other bonding means. The suture extension can reduce the total displacement due to stretching of the suture during deployment of the vascular closure device, enhancing the positional control and improving the reliability of the device deployment. The shearing block can be a static structure with a hole through which the suture passes, or it can have a shape or orientation change, such as from straight to angled, to reduce friction between the suture and the shearing block during cinching, yet obtain an angled hole orientation for effective cutting. Multiple components can be used to achieve a shape change, or the shearing block can rotate to reorient the hole, or the shearing block can deform to better capture and control the suture and facilitate cutting by the cutting element. A feature incorporated with the cutting element can push or actuate an orientation change for the shearing block hole, so that the reorientation happens automatically when the cutting element is pulled back.

The cutting surface portion of the cutting element can slide with respect to the shearing block; in one relative orientation the shearing block holds the suture away from the cutting element to prevent damage to the suture. In another relative orientation the cutting element passes across the hole in the shearing block to cut the suture. For example, by pulling on the proximal end of the cutting element, which is accomplished either automatically or by actuation of the delivery device handle, the cutting element is retracted a short distance to trim the suture at the location of the shearing block. The cutting element, shearing block, and excess suture are removed with the device sheath at the conclusion of the procedure.

The shearing block can have a sharp edge rather than the cutting element, or both can have a sharp edge.

The cutting element is typically withdrawn to trim the suture to length. However, most motions of the cutting element can be reversed in orientation, so that the cutting element can be advanced a short distance to trim the suture to length. The cutting or shearing edge(s) can be oriented for close contact on advancing or on retracting of one or more elements.

The suture can take a straight path through cutter components, or the suture can be displaced to take a curved or angled path through cutter components to facilitate the cutting.

The shearing block can be advanced or withdrawn a short distance against a stationary cutting element to trim the suture to length.

A manual actuation feature such as a grasping ring can be incorporated to provide additional movement or control in case the automatic actuation fails to completely trim the suture.

The suture cutting apparatus can be modified to provide for minimally-invasive or automated cutting of sutures, even if the sutures are not associated with an anchor plug cinch type of vascular closure device.

If any mechanical advantage for compressing and deploying the plug is desired, a pulley system, or gear system, or hydraulic system, or other mechanical system can be incorporated into the handle.

Various overall configurations of the handle can be used. For example, the apparatus can be shaped like a syringe, or have an angled handle like a gun, or have concentric sliding cylinders with flanges, or have a squeeze mechanism where two portions of the handle are squeezed together to actuate the cinching mechanism, or have other configuration as is convenient for the principle actuations of components: attachment of handle to insertion sheath, and proximal movement to snug anchor against the insertion sheath and the artery and retract sheath and deploy and cinch the plug. Other actuations can still happen automatically, such as suture tensioning, controlled travel for cinching and deployment, and releasing of the suture, in keeping with the present invention. Mechanical advantage can be incorporated if desired.

An alternate embodiment utilizes sliding finger hooks, where the finger hooks slide in channels in the handle, where the sliding action automatically actuates a short distance retraction to provide the gap for plug deployment.

For plug materials which are more compressible, an automatic pre-compression action can be provided to pre-compress the plug prior to retraction of the sheaths.

Alternative cinch mechanisms other than the cinch disk include a cinch knot, a friction disk, a crimp, a friction tube, thermal forming, and elastic "spring" actuation, and combinations.

The plug can enhance hemostasis by swelling and physically filling space. Alternatively, the plug can expand from a crumpled, folded or other compressed state to a less-crumpled, folded, or otherwise compressed state to fill space for improved hemostasis. Thrombosis-promoting surfaces, morphology, chemistry, or medication can be incorporated to promote clotting for improved hemostasis. Combinations of hemostasis enhancement means can be utilized.

Indicators can be added to the device to inform the user of certain successful operations, or steps not performed, such as alignment markings, windows, flags, tabs, sounds, colors, snaps and stops felt by the hand, and so forth. These indicators could indicate locking of the hub, seating of the anchor, advancement of the push rod, and so forth.

Various combinations of the cited elements, features, and methods can be utilized, together with other enhancements and features as are known in the art.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A system for installing a vascular closure device, the vascular closure device adapted for sealing an opening in biological tissue and comprising an anchor, a compressible plug, a cinch and a suture, the system comprising:

the vascular closure device;

a housing attached to the suture at a proximal end of the housing;

a tubular member extending distally from the housing,

wherein when the anchor is seated against the biological tissue, pulling proximally on the housing causes the tubular member to retract into the housing and expose the plug, and

wherein a distance between the anchor and the proximal end of the housing remains unchanged when pulling proximally on the housing.

2. The system of claim **1**, wherein retracting the tubular member into the housing reduces a distance between a distal end of the tubular member and the proximal end of the housing.

3. The system of claim **1**, further comprising a releasable latch between the housing and the tubular member and a compressed biased member, wherein the latch is configured to release at a predetermined force level to allow the compressed biased member to expand to retract the tubular member into the housing.

4. The system of claim 1, further comprising a pusher tube disposed in the housing and in the tubular member,

wherein pulling proximally on the housing causes the pusher tube to move distally with respect to the housing to compress the plug.

5. The system of claim 4, further comprising a releasable latch member and a compressed bias member, wherein the latch is configured to release at a predetermined force level to allow the compressed bias member to expand and force the pusher tube distally to compress the plug.

6. The system of claim 5, further comprising a suture cutting system,

the suture cutting system comprising,

a stop fixed with respect to the housing;

a shearing block fixed with respect to the tubular member;

a blade disposed within the block;

an elongate member attached to the blade and extending proximally therefrom, the elongate member having a proximal end attached to an element disposed about a proximal portion of the pusher tube proximal the stop,

wherein proximal movement of the pusher tube causes relative movement of the shearing block and blade to cut the suture.

7. The system of claim 6, wherein the suture extends through the blade and the shearing block.

8. The system of claim 1, further comprising a first releasable latch between the housing and the tubular member and a first compressed biased member, wherein the first latch is configured to release at a first predetermined force level to allow the first compressed biased member to expand to retract the tubular member into the housing and a second releasable latch member and a second compressed bias member, wherein the second latch is configured to release at a predetermined force level to allow the second compressed bias member to expand and force the pusher tube distally to compress the plug,

wherein the second predetermined force level is greater than the first predetermined force level.

9. The system of claim 1, further comprising means for automatically seating the anchor on the tubular member.

10. The system of claim 1, wherein the housing includes a device sheath; and

whereby the tubular member and the device sheath are configured such that the advancement of the device sheath within the tubular member and the subsequent retraction of the combination of the tubular member and the device sheath seat the plug in the opening.

11. The system of claim 10, wherein the tubular member comprises an insertion sheath tube, an insertion sheath hub and a bias member compressed between the insertion sheath tube and the insertion sheath hub, whereby the insertion sheath tube and insertion sheath hub are fixed together at a releasable latch point that is released upon the application of a first force and that, when released, allows the bias member to expand.

12. The system of claim 11, wherein the bias member operates to retract the device sheath inside the insertion sheath tube when the latch is released.

13. The system of claim 11, further comprising a pusher tube attached to the device sheath by a second releasable latch, the pusher tube and the device sheath together confining a second bias member in a compressed position, the second latch releasable upon application of a second force to allow the second bias member to move the pusher tube distally relative to the device sheath, where the pusher tube has a distal end movable to contact the cinch.

14. The system of claim 13, further comprising means for automatically cutting the suture upon release of the second latch.

15. The system of claim 11, wherein the insertion sheath tube has a beveled distal end.

16. The system of claim 10, wherein the bias member is a spring.

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